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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,265	08/31/2001	Timothy A. Springer	CBN-002CP	1985

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EXAMINER
HADDAD, MAHER M

ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 06/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/945,265	Applicant(s) SPRINGER ET AL.	
	Examiner Maher M. Haddad	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-72 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Restriction Requirement

1. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Applicant is reminded that "use" claims are non-statutory and are not appropriate for US practice (see MPEP 2173.05(q)).

For examination purposes "use" claims are interpreted as a method of the first recited "use".

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7, 10, 16-19, 21 and 23, drawn to a modified integrin I-domain polypeptide which is derived from an I-domain of the α1; classified in Class 530, subclasses 395.

II. Claims 1-7, 10, 16-19, 21 and 23, drawn to a modified integrin I-domain polypeptide which is derived from an I-domain of the α2; classified in Class 530, subclasses 395.

III. Claims 1-7, 10, 16-19, 21 and 23, drawn to a modified integrin I-domain polypeptide which is derived from an I-domain of the α10; classified in Class 530, subclasses 395.

IV. Claims 1-7, 10, 16-19 21 and 23, drawn to a modified integrin I-domain polypeptide which is derived from an I-domain of the α11; classified in Class 530, subclasses 395.

V. Claims 1-7, 10, 16-19, 21 and 23, drawn to a modified integrin I-domain polypeptide which is derived from an I-domain of the αD; classified in Class 530, subclasses 395.

VI. Claims 1-7, 10,16-19, 21 and 23, drawn to a modified integrin I-domain polypeptide which is derived from an I-domain of the αE; classified in Class 530, subclasses 395.

VII. Claims 1-11, 16-19, 21 and 23, drawn to a modified integrin I-domain polypeptide which is derived from an I-domain of the αL (CD11a); classified in Class 530, subclasses 395.

VIII. Claims 1-7, 10, 12-19, 21 and 23, drawn to a modified integrin I-domain polypeptide which is derived from an I-domain of the αM (CD11b); classified in Class 530, subclasses 395.

IX. Claims 1-7, 10, 16-19, 21 and 23, drawn to a modified integrin I-domain polypeptide which is derived from an I-domain of the αX (CD11c); classified in Class 530, subclasses 395.

X. Claims 20, 22 and 65-67, drawn to an isolated nucleic acid molecule encoding modified integrin I-domain polynucleotide of α1; classified in Class 536, subclass 23.5.

XI. Claims 20, 22 and 65-67, drawn to an isolated nucleic acid molecule encoding modified integrin I-domain polynucleotide of α2; classified in Class 536, subclass 23.5.

XII. Claims 20, 22 and 65-67, drawn to an isolated nucleic acid molecule encoding modified integrin I-domain polynucleotide of α10; classified in Class 536, subclass 23.5.

XIII. Claims 20, 22 and 65-67, drawn to an isolated nucleic acid molecule encoding modified integrin I-domain polynucleotide of α11; classified in Class 536, subclass 23.5.

XIV. Claims 20, 22 and 65-67, drawn to an isolated nucleic acid molecule encoding modified integrin I-domain polynucleotide of αD; classified in Class 536, subclass 23.5.

XV. Claims 20, 22 and 65-67, drawn to an isolated nucleic acid molecule encoding modified integrin I-domain polynucleotide of αE; classified in Class 536, subclass 23.5.

XVI. Claims 20, 22 and 65-67, drawn to an isolated nucleic acid molecule encoding modified integrin I-domain polynucleotide of αL (CD11a); classified in Class 536, subclass 23.5.

XVII. Claims 20, 22 and 65-67, drawn to an isolated nucleic acid molecule encoding modified integrin I-domain polynucleotide of αM (CD11b); classified in Class 536, subclass 23.5.

XVIII. Claims 20, 22 and 65-67, drawn to an isolated nucleic acid molecule encoding modified integrin I-domain polynucleotide of αX (CD11c); classified in Class 536, subclass 23.5.

XIX. Claims 24-28, drawn to an antibody, or antigen binding fragment thereof, wherein said antibody is an α1 antibody, and a method of producing; classified in Class 530, subclass 387.1.

XX. Claims 24-28, drawn to an antibody, or antigen binding fragment thereof, wherein said antibody is an α2 antibody, and a method of producing; classified in Class 530, subclass 387.1.

XXI. Claims 24-28, drawn to an antibody, or antigen binding fragment thereof, wherein said antibody is an α10 antibody, and a method of producing; classified in Class 530, subclass 387.1.

XXII. Claims 24-28, drawn to an antibody, or antigen binding fragment thereof, wherein said antibody is an α11 antibody, and a method of producing; classified in Class 530, subclass 387.1.

XXIII. Claims 24-28, drawn to an antibody, or antigen binding fragment thereof, wherein said antibody is an αD antibody, and a method of producing; classified in Class 530, subclass 387.1.

XXIV. Claims 24-28, drawn to an antibody, or antigen binding fragment thereof, wherein said antibody is an αE antibody, and a method of producing; classified in Class 530, subclass 387.1.

XXV. Claims 24-28, drawn to an antibody, or antigen binding fragment thereof, wherein said antibody is an αL antibody, and a method of producing; classified in Class 530, subclass 387.1.

XXVI. Claims 24-28, drawn to an antibody, or antigen binding fragment thereof, wherein said antibody is an αM antibody, and a method of producing; classified in Class 530, subclass 387.1.

XXVII. Claims 24-28, drawn to an antibody, or antigen binding fragment thereof, wherein said antibody is an αX antibody, and a method of producing; classified in Class 530, subclass 387.1.

XXVIII. Claims 24-31, drawn to an antibody, or antigen binding fragment thereof, wherein said antibody is an LFA-1 antibody, and a method of producing; classified in Class 530, subclass 387.1.

XXIX. Claims 32-37, drawn to a modified integrin I-like domain polypeptide, classified in Class 530, subclasses 395.

XXX. Claims 38-43, drawn to a method for stabilizing a polypeptide in a desired conformation wherein said polypeptide comprises an integrin I-domain; classified in Class 435, subclasses 40.51.

XXXI. Claims 38-41and 43, drawn to a method for stabilizing a polypeptide in a desired conformation wherein said polypeptide comprises a small G protein; classified in Class 435, subclasses 40.51.

XXXII. Claims 38-41 and 43, drawn to a method for stabilizing a polypeptide in a desired conformation wherein said polypeptide comprises a heterotrimeric G protein alpha subunit; classified in Class 435, subclasses 40.51.

XXXIII. Claims 38-41 and 43, drawn to a method for stabilizing a polypeptide in a desired conformation wherein said polypeptide comprises a tyrosine kinases; classified in Class 435, subclasses 40.51.

XXXIV. Claims 38-41 and 43, drawn to a method for stabilizing a polypeptide in a desired conformation wherein said polypeptide comprises a G protein-coupled receptor; classified in Class 435, subclasses 40.51.

XXXV. Claims 38-41 and 43, drawn to a method for stabilizing a polypeptide in a desired conformation wherein said polypeptide comprises an enzyme under allosteric control; classified in Class 435, subclasses 40.51.

XXXVI. Claims 38-41 and 43, drawn to a method for stabilizing a polypeptide in a desired conformation wherein said polypeptide comprises a zymogen; classified in Class 435, subclasses 40.51.

XXXVII. Claims 38-41 and 43, drawn to a method for stabilizing a polypeptide in a desired conformation wherein said polypeptide comprises complement C3; classified in Class 435, subclasses 40.51.

XXXVIII. Claims 38-41 and 43, drawn to a method for stabilizing a polypeptide in a desired conformation wherein said polypeptide comprises complement C4; classified in Class 435, subclasses 40.51.

XXXIX. Claims 38-41 and 43, drawn to a method for stabilizing a polypeptide in a desired conformation wherein said polypeptide comprises fibrinogen; classified in Class 435, subclasses 40.51.

XL. Claim 44, drawn to a method for identifying a modulator of integrin activity; classified in Class 435, subclasses 7.1.

XLI. Claim 45, drawn to a method for identifying a compound capable of modulating interaction of an integrin and a cognate ligand, classified in Class 435, subclasses 7.1.

XLII. Claim 46-47 and 50-53, drawn to a method of treating or preventing an integrin-mediated disorder in subject as it reads on an inflammatory disorder and the modified integrin I-domain is αL, classified in Class 514, subclasses 2.

XLIII. Claim 46-47 and 50-53, drawn to a method of treating or preventing an integrin-mediated disorder in subject as it reads on an inflammatory disorder and the modified integrin I-domain is αM, classified in Class 514, subclasses 2.

XLIV. Claim 46, 48 and 50-53, drawn to a method of treating or preventing an integrin-mediated disorder in subject as it reads on an autoimmune disorder and the modified integrin I-domain is αL, classified in Class 514, subclasses 2.

XLV. Claim 46, 48 and 50-53, drawn to a method of treating or preventing an integrin-mediated disorder in subject as it reads on an autoimmune disorder and the modified integrin I-domain is αM, classified in Class 514, subclasses 2.

XLVI. Claim 49-53, drawn to a method of inhibiting the binding of an integrin to a cognate ligand in a subject wherein the modified integrin I-domain is αL, classified in Class 514, subclasses 2.

XLVII. Claim 49-53, drawn to a method of inhibiting the binding of an integrin to a cognate ligand in a subject wherein the modified integrin I-domain is αM, classified in Class 514, subclasses 2.

XLVIII. Claims 54-57, 59-61 and 64, drawn to a method for treating or preventing an integrin-mediated disorder in a subject comprising administering to a subject an antibody wherein said integrin-mediated disorder is inflammatory disorder, classified in Class 424, subclasses 130.1.

XLIX. Claims 54-56, 58-60 and 64, drawn to a method for treating or preventing an integrin-mediated disorder in a subject comprising administering to a subject an antibody wherein said integrin-mediated disorder is autoimmune disorder, classified in Class 424, subclasses 130.1.

L. Claims 62-64 , drawn to a method of inhibiting of an integrin to a cognate ligand in a subject comprising administering to said subject an effective amount of an antibody; classified in Class 424, subclasses 130.1.

LI. Claims 68-70, drawn to a method for treating an integrin-mediated disorder in a subject comprising administering to said subject a nucleic acid molecule; classified in Class 514, subclasses 44.

LII. Claims 71-72, drawn to non-human, transgenic animal comprising a nucleic acid molecule encoding a modified integrin I-domain polypeptide; classified in Class 800, subclasses 18.

4. Groups I-XXIX and LII are different products. Polypeptides, nucleic acids, antibodies to the polypeptides differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

5. Groups XXX- LI are different methods. A method for stabilizing and a method for identifying, a method for treating or preventing, a method of inhibiting differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. Groups VII/XLII, VII/XLIV, VII/XLVI, XXVIII/XLVIII-L and X-XVIII/LI are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group XIX can be used for affinity purification, in addition to the methods of treating and inhibiting recited.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

8. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If anyone of Groups I-IX is elected, applicant is required to elect a modified integrin I-domain polypeptide which contains a specific amino acid substitution as recited in claim 10. These substitutions are distinct species because their structures and modes of action are different.

B. If anyone of Groups XLII or XLIV is elected, applicant is required to elect a method for treating or preventing an integrin-mediated disorder in subject wherein the modified integrin is 1) αL K287C/K294C, 2) αL E284C/E301C. 3) αL L161C/F299C, 4) αL K160C/F299C, or 5) αL L161C/Y300C. These substitutions are distinct species because their structures and modes of action are different.

C. If anyone of Groups XLIII or XLV is elected, applicant is required to elect a method for treating or preventing an integrin-mediated disorder in subject wherein the modified integrin is 1) αM Q163C/Q309C, or 2) αM D294C/Q311C. These substitutions are distinct species because their structures and modes of action are different.

D. If Group XLVI is elected, applicant is required to elect a method of inhibiting an integrin to a cognate ligand in subject wherein the modified integrin is 1) αL K287C/K294C, 2) αL E284C/E301C. 3) αL L161C/F299C, 4) αL K160C/F299C, or 5) αL L161C/Y300C. These substitutions are distinct species because their structures and modes of action are different.

E. If Group XLVII is elected, applicant is required to elect a method of inhibiting an integrin to a cognate ligand in subject wherein the modified integrin is 1) αM Q163C/Q309C, or 2) αM D294C/Q311C. These substitutions are distinct species because their structures and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 36 is generic.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
June 6, 2002

Christina Chan

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